DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

September 18, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-40

Herbert Eckmann, President
Alaska Sausage & Seafood Company, Inc.
2914 Arctic Boulevard
Anchorage, Alaska 99503

WARNING LETTER

Dear Mr. Eckmann:

We inspected your firm, Alaska Sausage & Seafood Company, Inc, located at 12914 Arctic Boulevard, Anchorage, Alaska, on June 16-20, 2003. As part of that inspection, finished product sample 195101 of kippered halibut was collected and analyzed for Listeria monocytogenes and water phase salt (WPS). The analysis revealed the product to be negative for Listeria monocytogenes; however, the WPS analysis found ten of ten packages of kippered halibut with water phase salt levels below 3.5%. It appears you are not adequately controlling water phase salt during the brining process of your kippered halibut, which may support the formation of toxin by Clostridium botulinum, a significant food safety concern. FDA believes you need to re-evaluate your brining time and salinity measurement to see why you are not consistently achieving 3.5% water phase salt in these products. On or about July 15, 2003, you were sent reports of the sample analysis from the FDA Pacific Regional Laboratory-Northwest informing you of these results.

During the inspection, we also found that you had serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations), as well as some Good Manufacturing Practice (GMP) deficiencies. A FDA 483 form (copy enclosed) listing the deviations was presented to Mr. Cameron W. Vivian, Plant Manager, at the conclusion of the inspection.

These deviations cause your products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov. The deviations were as follows:

1. **You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." Although your firm's HACCP plan for vacuum packed smoked salmon and vacuum packed smoked halibut lists a critical limit at the brining critical control point, that critical limit is not adequate to control Clostridium botulinum.**

   a) **Your HACCP plan for smoked salmon and halibut does not list the critical limits of brine pressure and the belt speed of the brine injection machine. The brine formulation, brine pressure, and the belt speed of the brine injection machine are all necessary elements in the proper use of a brine injection machine. The mechanical brining process, when performed properly, coupled with the drying performed in the smokehouse, produce a finished product with a water phase salt level (≥3.5%), needed to control Clostridium botulinum.**

   b) **Moreover, FDA has additional evidence that the critical limits at your brining critical control point are seriously inadequate. The following are the results of the laboratory testing performed on samples collected on June 19, 2003:**

Sub-sample number	% WPS	%WPS (check sample)
1.	2 .4	2.4
2.	2.2	2.2
3.	2.2	2.3
4.	2.3	2.3
5.	2.0	2.3
6.	2.3	2.1
7.	2.5	2.2
8.	2.5	2.4
9.	2.6	2.6
10.	2.3	2.4

Based on the water phase salt (WPS) analysis for sample 195101, vacuum packaged hot smoked halibut collected at your firm on

June 19, 2003, we have determined that the analysis was performed correctly and the highest WPS level in any of the ten (10) sub-samples was 2.6%.

2. **You must implement the recordkeeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6 (b). However, your firm did not record monitoring observations at the storage critical control point to control Clostridium botulinum, as listed in your HACCP plan for smoked fish. This is evidenced by the fact that the temperature control charts for May 5 through May 12 are missing and the control chart for May 13 is blank. The only temperature monitoring records that exist for those days are entries in the sanitation monitoring records. These entries, which appear to be altered, show that the cooler temperatures spiked to at least 44° on both May 12 and 13.**

3. **You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit of water phase salt for kippered halibut at the "Brining" critical control point (CCP) to control Clostridium botulinum growth and toxin production. Specifically, your firm did not verify the WPS levels for kippered halibut semi-annually as directed by the HACCP plan. Your firm did not have any WPS test results for your kippered halibut.**

4. **You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for the prevention of cross contamination or the protection of food, food packaging, and food contact surfaces required for the processing of smoked fish. This is evidenced by the fact that these issues are not addressed in any of your firm's sanitation monitoring records.**

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: ADEC A with disclosure statement